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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,392	11/22/2006	Kun Yu	0380-P04018US00	9152
110 7590 06/20/2007 DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			EXAMINER AEDER, SEAN E	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 06/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,392

Applicant(s)

YU ET AL.

Examiner

Sean E. Aeder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-20 and 22-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,5-20 and 22-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Note: To expedite prosecution, Applicant is advised to submit SEQ ID NOs corresponding to any elected genes with the response to this Restriction Requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

It is noted that the claims of the instant application have been determined to include linking claims. Claims 1, 12, 16, 23, 28, and 32 link(s) inventions I-II, as set forth below.

The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim X. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no

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longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group I, claim(s) 2, 5-11, 13-15, 17-20, 22, 24-27, 29-31, and 33-37 drawn to a method for determining the prognosis of a patient based on the polynucleotide levels of genes from a prognostic set and a kit for performing said method, a method of producing a nucleic acid expression profile for a breast tumor sample comprising identifying the expression levels of a prognostic set of genes, and a method for identifying a set of genes that are differentially expressed at the polynucleotide level within a group of tumors.

(Note: Upon election of group I, Applicant must elect a single prognostic set of genes, as each prognostic set represents a separate invention and not a species.)

Group II, claim(s) 2, 5-11, 13, 14, 17-20, 24-27, 29, 31, and 33-37 drawn to a method for determining the prognosis of a patient based on the polypeptide levels of genes from a prognostic set and a kit for performing said method, a method of producing a protein expression profile for a breast tumor sample comprising identifying the expression levels of a prognostic set of genes at the polypeptide level, and a method for identifying a set of genes that are differentially expressed at the polypeptide level within a group of tumors.

(Note: Upon election of group II, Applicant must elect a single prognostic set of genes, as each prognostic set represents a separate invention and not a species.)

The inventions listed as groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: groups I-II encompass different special technical features as identified in the groupings above. The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because under unity of invention between different *categories* of inventions unity of invention will only be found to exist if specific combinations of inventions are present.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said

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product, and an apparatus or means specifically designed for carrying out the said process. The allowed combinations do not include multiple products (such as multiple expression profile databases) and multiple methods of using said products (such as multiple methods of determining a prognosis using various prognostic sets), as claimed in the instant application. The products themselves do not share significant structural elements to the extent that each member could be substituted, one for the other, with the expectation that the same intended results would be achieved. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application is considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I is the main invention. After that, all other products and methods are broken out as separate groups (see 37 CFR 1.475(d)).

Therefore, a method for determining the prognosis of a patient based on the polynucleotide levels of genes from a prognostic set and a kit for performing said method, a method of producing a nucleic acid expression profile for a breast tumor sample comprising identifying the expression levels of a prognostic set of genes, and a method for identifying a set of genes that are differentially expressed at the polynucleotide level within a group of tumors is considered the "main invention" and the remaining products and methods have been properly restricted into separate groups.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SEA
/Misook Yu/
Primary Examiner, Art Unit 1642